BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,542	09/15/2000	Mark D. Fidock	PC10349AGPR	3854

7590 07/03/2003

Gregg C Benson
Pfizer Inc
Patent Department
MS 4159 Eastern Point Road
Groton, CT 06340

EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	**PAPER NUMBER**
1636	16

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,542	FIDOCK ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,19-22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-12,14,19,20,22 and 24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13,15 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response filed on 04/24/03 has been acknowledged.

Claims 1-4, 6-15, 19-22 and 24-26 are pending.
Claims 1, 13 15 and 21 are examined in this office action.

► *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm). Each amendment document that includes a change to an existing claim, or submission of a new claim,* ***must include a complete listing of all claims*** *in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1, 13, 15 and 21) in Paper No. 15 is acknowledged. The traversal is on the ground(s) that any search for the polypeptide of elected Group I will necessarily encompass any literature references that disclose nucleic acid sequences or method for identifying agents that affect the activity of PDEXV. The applicant argues that Group I and II should be recombined for the examination, as it is generally deemed necessary to search for both the amino acid and nucleic acid sequences. This is not found persuasive because nucleic acid and proteins are structurally and functionally distinct products. MPEP clearly states that inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In instant case polypeptides are biologically active compounds, whereas the nucleic acid requires an expression vector and host cells to produce the gene product. Therefore, these inventions are distinct and are of separate uses. Furthermore, the inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can also be isolated from a cell that naturally express the polypeptide rather than using recombinant means. In addition the polypeptides can also be used to make antibodies besides using in a method of screening compounds that affect PDEXV activity. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-4, 6-12, 14, 19-20, 22 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Specification

3. The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, on page 30, line 10 the specification contains a browser-executable code. In addition, the specification fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures (see attached notice to comply). Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1, 13 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 13 and 15, as written, do not sufficiently distinguish over PDE polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated PDE" or "Purified PDE". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 13, 15 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of invention as claimed encompasses an amino acid sequence presented as SEQ ID NO:1 or variant, homologue, fragment or derivative thereof, wherein the seqeucne comprises at least 25 contiguous amino acids selected from the amino acids 1-194 of SEQ ID NO:1. The scope of invention as claimed encompass any enzyme that have an immunological reaction with an antibody raised against PDEXV. In addition the scope of invention as claimed encompasses a PDEXV enzyme obtained form any and all organisms.

At best the specification disclosed only the amino acid sequences of SEQ ID NO:1 which encodes for a recombinant human PDEXV enzyme (spec. pages 70-75). The specification fails to disclose any variant of SEQ ID NO:1 isolated from any organism that has PDEXV-like activity explicitly or implicitly as putatively considered by the invention as claimed. Similarly the specification fails to disclose any enzyme that interacts with any and all antibodies raised against any and all epitopes of PDEXV polypeptide. In fact the specification fails to disclose a single antibody raised against PDEXV polypeptide (any and all epitopes). In addition the specification fails to disclose a recombinant PDEXV enzyme (other than human PDEXV) obtained from any and all organisms.

Applicant is referred to the guidelines for ***Written Description Requirement*** published January 5, 2001 in the Federal Register, Vol.66, No.4, Pg.1099-1110 (see http://www.uspto.gov). The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing.

(see In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000). In the instant case the specification only disclosed single variant of SEQ ID NO:1 which encodes for a recombinant human PDEXV enzyme (spec. pages 70-75). The possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Pfaff v. WellsElectronics, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).* In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (*Eli Lilly, 119 F.3d at 1568, 43 USPQ2d 130at 1406).*

In the instant case the amino acid variants (as claimed) has been defined only by a statement of function that broadly encompasses PDEXV-like activity or an immunological reaction with an antibody raised against PDEXV which conveyed no distinguishing information about the identity of the claimed amino acid sequences, such as its relevant structural or physical characteristics. The variation as claimed also encompasses the conserved motifs, which are

considered germane to the functional activity of PDEXV-like polypeptide. The invention as claimed encompasses an amino acid sequence which has sequence similarity with only 25 contiguous amino acid sequences selected from 1-194AA of SEQ ID:1 (684AA). Given the broadest reasonable interpretation the scope of invention as claimed encompasses an amino acid sequence which is only 13% identical (87% variation) to the amino acid sequences 1-194 of SEQ ID NO:1. Furthermore the scope of invention as claimed encompasses a an amino acid sequence which is only 3.6% identical (96.4% variation) to amino acid sequences of PDEX (SEQ ID NO:1, 684AA) over the entire length of 684 amino acids. Such a variation would certainly affect proper folding and biological activity if amino acids that are critical for such functions are substituted, since the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Furthermore, mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues (see Ngo, in The Protein Folding Problem and Tertiary Structure Prediction, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in Peptide Hormones, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976).

In addition, the instant specification fails to meet **Written Description Requirement for the deposited biological material**. see Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited

before the patent is granted." Id. at 34,876. "*The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement.*" Id. At 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., In re Lundak, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("*As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.*"). In instant case applicant's referral to the deposit of NCIMB 41025 on page 69 of the specification is insufficient assurance that all written description requirements for the deposited biological material has been met. It is unclear what is the nucleotide sequence of PDEXV deposited in the biological deposit made.

According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

6. Claims 1, 13 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a human PDEXV enzyme comprising the amino acid sequences of SEQ ID NO:1, does not reasonably provide enablement for any and all variants,

homologues or derivatives of SEQ ID NO:1, wherein such variants, homologues or derivatives are obtained from any and all organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature Of Invention:

Invention relates to a PDE enzyme (cyclic nucleotide phosphodiesterase).

Breadth Of Claims And Guidance Provided By The Inventor:

The scope of invention as claimed encompasses an amino acid sequence presented as SEQ ID NO:1 or variant, homologue, fragment or derivative thereof, wherein the seqeucne comprises at least 25 contiguous amino acids selected from the amino acids 1-194 of SEQ ID NO:1. The scope of invention as claimed encompass any enzyme that have an immunological reaction with an antibody raised against PDEXV. In addition the scope of invention as claimed encompasses a PDEXV enzyme obtained form any and all organisms.

At best the specification disclosed only single variant of SEQ ID NO:1 which encodes for a recombinant human PDEXV enzyme (spec. pages 70-75). The specification fails to disclose any variant of SEQ ID NO:1 isolated from any organism that has PDEXV-like activity explicitly or implicitly as putatively considered by the invention as claimed. Similarly the specification fails to disclose any enzyme that interacts with any and all antibodies raised against any and all epitopes of PDEXV polypeptide. In fact the specification fails to disclose a single antibody raised against PDEXV polypeptide or any variant thereof (any and all epitopes). In addition the specification fails to disclose a recombinant PDEXV enzyme (other than human PDEXV) obtained from any and all organisms.

State Of Art And Predictability:

Cyclic nucleotide phosphodiesterases (PDE) metabolize cAMP and cGMP, which are second messengers regulating many functions in various cells and tissues. Based on their amino acid sequence homology, biochemical properties, and inhibitor profiles, many kinds of PDEs have been identified in mammalian tissues. Each PDE is involved in controlling cyclic nucleotide levels and plays a distinct physiological role in different tissues and cells. Furthermore, the hydrolysis of cyclic nucleotides is multiply controlled by PDEs co-existing in the same cells. (Yuasa et al J. Biol. Chem., 275(40):31469-31479, 2000). Phosphodiesterase-11A (PDE11A) is a recently identified family of cAMP and cGMP hydrolyzing enzymes wherein two additional splice variants of PDE11A, PDE11A2 and PDE11A3 has been identified. The ORF of PDE11A2 and PDE11A3 predicts a protein of 576 aa and 684 respectively. Comparison of the PDE11A2 sequence with that of PDE11A1 indicates an additional 86 aa at the N terminus of PDE11A2. Compared with PDE11A2, PDE11A3 has an additional 108 N-terminal amino acids. Sequence analysis of PDE11A3 indicates the presence of another GAF domain in this region. This diversification of regulatory sequences in the N-terminal region of PDE11A splice variants suggests the possibility of differential regulation of these enzymes The PDE11A3 has a consensus catalytic domain that is located between amino acids 413 and 652. At the N-terminus PDE11A3 contains two GAF domains situated between amino acids 1-125 and 152-313(Hetman et al PNAS 97(23):12891-9, 2000 page 12893 fig-1).

The scope instant invention as claimed encompasses a PDEXV-like amino acid sequence which has sequence similarity with only 25 contiguous amino acid sequences selected from 1-194 of SEQ ID:1 (684AA). Given the broadest reasonable interpretation the scope of invention

as claimed encompasses an amino acid sequence which is only 3.6% identical (96.4% variation) to amino acid sequences of PDEXV (SEQ ID NO:1) over the entire length of 684 amino acids. The variations as claimed encompass both GAF and catalytic domains found in the PDEXV-polypeptide. Such a variation would certainly affect proper folding and biological activity if amino acids that are critical for such functions are substituted, since the relationship between the sequence of a polypeptide and its tertiary structure is neither well understood nor predictable. Furthermore, mere identification of critical regions would not be sufficient, as the ordinary artisan would immediately recognize that the encoded polypeptide must assume the proper three-dimensional configuration to be active, which is dependent upon the surrounding residues (see Ngo, in The Protein Folding Problem and Tertiary Structure Prediction, Merz et al. (eds.), Birkhauser Boston: Boston, MA, pp. 433 and 492-495, 1994). Rudinger (in Peptide Hormones, Parsons (ed.), University Park Press: Baltimore, MD, pp. 1-7, 1976). Furthermore, the specification fails to disclose a single antibody that would distinguish the PDEXV from other known PDEs, so that one skill in the art would identify any and all PDEXV-like polypeptides without undue experimentation. At best the specification teaches single variant of SEQ ID NO:1 which encodes for a recombinant human PDEXV enzyme and fails to disclose any PDEXV variants, homologues or derivatives are obtained from any and all organism

Quantity Of Experimentation Required:

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). In instant case screening of any and all natural and non-natural variants, wherein 96% of amino acid are added substituted and /or deleted in the disclosed SEQ ID NO:1 is not considered routine. Making and testing a point mutation is

significantly different from the making and testing an amino acid sequences wherein at least 96% amino acids are added, deleted and/or substituted. The number of possible scenario increase geometrically with increase in percent non-identity. Furthermore considering the limited disclosure, to screen a PDEXV-like polypeptide using an antibody raised against PDEXV would requires further undue experimentation (to make PDEXV-specific antibody), since the specification fails to disclose a single antibody that distinguishes the PDEXV over other known PDEs. Such making and testing is nothing more than an invitation to further experimentation, since the specification can not be relied on to teach how to make the variants as claimed. One has to engage in extensive making and testing in order to obtain variants that meet the requirements for the claimed PDEXV-activity. This is not considered routine in the art and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. Therefore, the applicant has not presented enablement commensurate in scope with the claims.

7. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's referral to the deposit of NCIMB 41025 on page 69 of the specification is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. Therefore one skill in the art would not be able to exercise the invention as claimed.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicant, Assignee, or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty, as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in Applicant's possession at the time of filing. See In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;
d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,
e) the deposit will be replaced it should ever become inviable.

Notice To Comply

With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

8. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

> Specifically the application fails to comply with CFR 1.821(d), which states:
> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application (see MPEP 2422.03).
> For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).
> The instant specification fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures. *For example, the specification discloses nucleotide and/or amino acid sequences on pages 15, 20 and 70-71, However, these sequences are not identified by sequence identifiers (SEQ ID NO). In addition, it is unclear whether these sequences are disclosed in the sequence listing as submitted with the instant specification.*

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
PATENT EXAMINER

SUMESH KAUSHAL
PATENT EXAMINER